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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,348	02/14/2002	Jotham W. Coc	PC10030D	9919

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,348	Applicant(s) WADSWORTH ET AL.	
	Examiner Brenda Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10,15-23 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10,15-23 and 25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6, 8, 10, 15-23 and 25-35 are pending in the application.

This action is in response to applicants' amendment filed October 25, 2004.

Claim 1 has been amended and claim 24 has been canceled.

Response to Arguments

Applicants' arguments filed October 25, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1) maintained in the last office action, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that the specific compounds that are embraced by the cited classes are common knowledge to those skilled in the art. However, the additional active ingredient within the terms a **muscarinic agonist**, a **neurotrophic factor**, an **agent that slows or arrests Alzheimer's disease**, an **amyloid aggregation inhibitor**, a **secretase inhibitor**, a **tau kinase inhibitor**, a **neuronal anitainflammatory agent** and an **estrogen-like therapeutic agent** is not defined in the specification. The terms are of indeterminate scope.

The applicants point to several journal articles for support in the use of some of the terms listed above. However, these references "Muscarinic agonists and antagonists in the treatment of Alzheimer's disease", W. Greenlee, et al, *Il Farmaco* vol. 56, #4, **April 1, 2001**, pp247-250; "Therapeutic Strategies in Alzheimer's Disease: M1 Muscarinic Agonists", A. Fisher, *Jpn. J. Pharmacol.* Vol. 84, 101-112 (**2000**); " β -Amyloid

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Aggregation Inhibitors for the Treatment of Alzheimer's Disease: Dream or Reality?" P. Talaga, *Mini Reviews in medicinal Chemistry*, Vol.1, 175-186 (2001); "Muscarinic agonists- a logical approach for AD?" A. Korczyn, *Alzheimer Insights Online*, vol. 7, No. 4 (see References), a catalog entry for commercially available secretase inhibitors which provides references (see references 2-5) on a specific secretase inhibitor and an abstract of the article "Limited efficacy of pentoxifylline as anti-inflammatory agent in experimental pneumococcal meningitis, G. Zysk, et al., *Clin Exp Immunol.*, Vol. 107(3), 458-461 (1997). The Applicants' argue that the references detailing the use of the terms outlined above are sufficient in the enablement of the claimed invention. The applicant's arguments in reference to the journal articles other than the efficacy of pentoxifylline as an anti-inflammatory agent are not persuasive in that the articles were not public knowledge at the time of filing. See MPEP 2164.05(a)

2164.05(a) Specification Must Be Enabling as of the Filing Date

The state of the art, existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. In re Gunn , 537 F.2d 1123, 1128, 190 USPQ 402, 405 06 (CCPA 1976); In re Budnick, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.). While a later dated publication cannot supplement an insufficient disclosure in a prior

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dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).

The nature of the instant invention, has claims which embrace substituted 10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-triene compounds. The instant compounds of formula (I) wherein the additional active ingredients are not described in the disclosure in such a way the one of ordinary skill in the art would not know how to prepare the various compounds suggested by claims 1-6, 8, 10 and 15-35. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention.

Claims 1-6, 8, 10, 15-23 and 25-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. With regards to the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, labeled paragraph 4) maintained in the last office action, the applicants' requested that this rejection be held in abeyance at this time.

Claims 1-6, 8, 10, 15-19, 22, 25-28 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,381, for reasons of record and stated above.

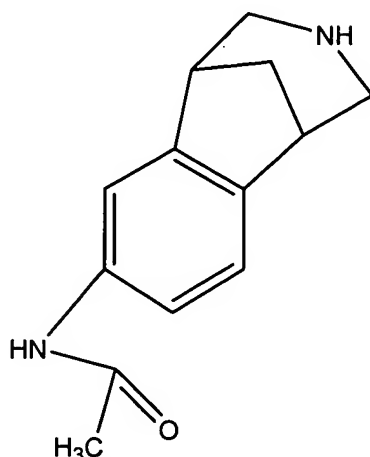
3. With regards to the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, labeled paragraph 5) maintained in the last office action, the applicants' requested that this rejection be held in abeyance at this time.

Claims 1-6, 8, 10, 15-19, 22, 25-28 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,399, for reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a) and b) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled c) the applicant's amendments and remarks have been fully considered but they are not persuasive.

c) The applicants' stated that claim 1 recites that formula 1 may have $R^1 = H$, $R^2 = H$ and $R^3 = -CONR^5R^6$ wherein R^5 may be H and R^6 may be C_1 alkyl which corresponds to the compound N^1 -[10-azatricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-trien-4-yl]acetamide. However, the nomenclature is such that the 10-azatricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-trien-4-yl ring system is attached to the

nitrogen atom of the acetamide as shown by the nomenclature assigned by ChemDraw.



N-(10-Aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-trien-4-yl)-acetamide.

Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Brenda Coleman
Primary Examiner Art Unit 1624
January 6, 2005